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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)				
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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto				
TITLE OF THE INVENTION (500 characters max)				
METHOD FOR PLACING MULTIPLE IMPLANT DURING A SURGERY USING A COMPUTER AIDED SURGERY SYSTEM				
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<input checked="" type="checkbox"/> Specification Number of Pages	15	<input type="checkbox"/> CD(s), Number		
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.				
<input checked="" type="checkbox"/> No				
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____				

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME

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TELEPHONE

514-847-4244/514-847-4333

Date

August 26, 2002

REGISTRATION NO.
If appropriate)

38,796

Docket Number:

15228-15uspr
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[SOR.PAT.FORM 110 - 10/2001]

METHOD FOR PLACING MULTIPLE IMPLANTS DURING A SURGERY USING A COMPUTER AIDED SURGERY SYSTEM

FIELD OF THE INVENTION

- [001] The invention relates to placing multiple implants during a surgery. More specifically, it relates to aligning multiple virtual implants together using a computer-aided surgery system in order to more precisely place the actual implants.

BACKGROUND OF THE INVENTION

- [002] There are a variety of computer-aided surgery systems that exist for assisting a surgeon in a surgery. Such systems allow the surgeon to view the anatomy of a patient before surgery in order to plan the procedure and during surgery in order to be guided throughout the procedure.
- [003] Surgical navigation is based on displaying, in real-time, instruments and patient anatomy to allow unobstructed visualization of the complete surgical field. Patient anatomy can be obtained from a number of sources, such as CT-scan, digitization, fluoroscopy, etc. Patient bone position and orientation are measured in real-time. They are used as references so that patient movement will not impact the navigation accuracy. Instrument position and orientation are also measured in real-time. This is used to display the instrument position relative to the patient bone on the computer screen.
- [004] Currently, systems allow surgeons to place a virtual implant in an image, select the implant from a group of virtual implants, and simulate the movement of a bone with the virtual implant. The virtual implant is placed with respect to its target bone. However, when there is more than one implant to be placed, and these implants are related to each other, it would be ideal to align the implants together in an optimal way.
- [005] Moreover, since it is essential to place implants with extreme precision, there

is a need to provide additional tools to surgeons in order to allow them to optimize the placements of the implants.

SUMMARY OF THE INVENTION

- [006] Accordingly, an object of the present invention is to provide additional planning tools for surgeons within a computer-aided surgery system.
- [007] Another object of the present invention is to align multiple virtual implants with respect to each other in an image.
- [008] According to a first broad aspect of the present invention, there is provided a method for placing multiple implants during a surgery using a computer aided surgery system, the method comprising: (a) providing an image representing a patient's anatomy; (b) selecting a virtual implant from a database of virtual implants; (c) placing said virtual implant in said image; (d) repeating steps (a) to (c) for subsequent virtual implants, taking into account a position of a preceding virtual implant to place a subsequent virtual implant using automated planning tools in said computer aided surgery system to determine one of a position and a shape of the subsequent virtual implant with respect to the preceding virtual implant; and (e) placing said multiple implants according to said virtual implants in said image using said computer aided surgery system.
- [009] Preferably, determining one of a position and a shape of the subsequent virtual implant further comprises using lines to join together said virtual implants and align them on said image representing a patient's anatomy. Alternatively, determining one of a position and a shape of the subsequent virtual implant further comprises calculating a location for said subsequent virtual implant based on a location of said preceding virtual implant. determining one of a position and a shape of the subsequent virtual implant further comprises constraining said one of a position and a shape based on constraints imposed by said preceding virtual implant.

- [010] The method also comprises re-adjusting a position of said preceding virtual implant to better position said subsequent virtual implant in order to achieve an optimal alignment of all of said virtual implants.
- [011] According to a second broad aspect of the present invention, there is provided an apparatus for planning a surgery, the apparatus comprising: a display for an image representing a patient's anatomy; a database of virtual implants from which a user selects; a tool for the user to manipulate in order to select the virtual implants from the database and place them in the image at chosen locations; and a positioning module to calculate a position of one of the virtual implants with respect to another of the virtual implants and allow the user to align the virtual implants with respect to each other for said planning a surgery.
- [012] Preferably, positioning module has a display module to indicate relative position data and the positioning module has a vector module to move virtual implants according to its calculations.
- [013] Also preferably, the planning module is used with a computer aided surgery system and a tracking module.

BRIEF DESCRIPTION OF THE DRAWINGS

- [014] These and other features, aspects and advantages of the present invention will become better understood with regard to the following description and accompanying drawings wherein:
- [015] FIG. 1 is an interface image showing three virtual screws in the pedicles;
- [016] FIG. 2 is an interface image showing a drill guided by a bull's eye;
- [017] FIG. 3 is an interface image showing a straight line used to align two virtual screws;
- [018] FIG. 4 is a block diagram of the apparatus;
- [019] FIG. 5 is a flow-chart according to the method of the present invention; and
- [020] FIG. 6 is a block diagram of a system using the apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

- [021] Throughout this application, the preferred embodiment of the present invention will be referred to as a "fluoro-spine application" of a "Navitrack™ system".
- [022] The Navitrack™ product is a device used intra-operatively to provide the surgeon with additional precise information concerning his maneuvers. Basically, it displays patient anatomy (obtained from pre or intra-operative images) and overlays the real time position of the surgeon's instruments. In addition, quantitative data relevant to the surgery is displayed on the screen. The fluoro-spine has the objective of giving navigation capabilities for the surgeon's instruments on intra-operative images. This is particularly useful for simple cases that can be operated without the optimal accuracy gained from a more radiation intensive scan like CT (computed tomography) or in trauma situations.
- [023] In a preferred embodiment, tracking is done with a POLARIS optical tracking system. POLARIS detects infrared light emitted by an active tracker or reflected by a passive tracker. Three dimensional position in space can only be evaluated when a minimum of three spheres or LEDs are seen by the camera. Clear line of sight is required, so no object can be placed between the camera and the trackers.
- [024] The principles of navigation and fluoroscopy are based on a tracked device placed over the intensifier of a C-arm. Plates with lead beads fitted to this device allow to position markers in known locations in the image.
- [025] Calibration of the image is done by computing the cone of projected x-rays. This step allows all virtual objects to be projected accurately on the C-arm images. From the markers, the x-ray volume is computed. Depending on the instrument position in the x-ray volume, its appearance may vary.
- [026] More specifically, calibration with the fluoroscope is done in several steps. A

first shot is taken. The computer realizes that an image was taken. The computer asks the tracking system the position and orientation of the clamp and the tracker on the C-arm. The computer then acquires the image. Image processing is done to find the positions of artifacts with respect to the known position of the C-arm tracker. The system can then extrapolate the position of a cone with respect to the camera reference coordinate system. The position of the cone with respect to the clamp can then be redefined.

[027] An x-ray sensitive diode may be integrated into the system in order to increase the speed of image detection by the system. The goal is to minimize the accuracy reduction caused by patient motion (ex: breathing) when the tracking system records the reference tracker position.

[028] The process for navigated fluoroscopy for spinal operations goes as follows. Patient data is first entered into the system. An awl or drill guide is calibrated, as well as a screw-driver. When the patient has been prepared, a vertebral clamp is placed. Fluoroscopy shots are taken and automatically transferred to the Navitrack™ system. Image calibration is performed automatically by the Navitrack™ system. The calibration of the shots to be used for navigation is then validated. For each necessary screw, the surgeon navigates his tool to position a virtual implant which is used to determine true implant size. The surgeon then leaves this virtual implant in the form of an axis on the navigated images. With the screw-driver, the surgeon navigates the real implant to match the planned axis. The outline of this implant is left on the images. When all screws are placed for the calibrated fluoroscopy shots, the surgeon takes a snapshot of the desired views for intra-operative documentation. Then it is back to the acquisition of fluoroscopy shots to operate the next vertebral segment.

[029] The basic technical steps for this type of application are the following:

1. Calibration of the surgeon's instruments to the tracking system coordinate system

2. Image acquisition from the fluoroscope by the navigation system
 3. Dewarping of acquired image
 4. Calibration of image to tracking system coordinate system
 5. Removal of calibration object patterns from images
 6. Navigation of the surgeon's instruments on the fluoroscope images
- [030] 1- Calibration of the surgeon's instruments to the tracking system coordinate system: Trackers are included on all the tools that the surgeon will use during the navigation. In order to properly display the information relative to these instruments, it is necessary to establish the mathematical relationship between each tracker and its corresponding tool tip position and orientation. This procedure is called calibration of the instruments. Basically, the tracker's position and orientation is measured by the tracking system while, simultaneously, the tool tip's position and orientation is in a position and orientation known by the tracking system.
- [031] 2- Image acquisition from the fluoroscope by the navigation system: Before proceeding with the image acquisition, a calibration object must be installed on the fluoroscope. This frame contains active trackers and 2 radio-transparent plates with a number of radio-opaque beads and/or wires. A calibration procedure is designed to establish the bead/wire position relative to the active tracker.
- [032] The NavitrackTM monitors the fluoroscope to detect when a shot is taken. At this moment, the position and orientation of all the trackers must be measured with the tracking system. In any case, the patient reference and calibration object position and orientation must be measured by the tracking system at the time of the shot to allow dewarping and calibration. The image is transferred to the NavitrackTM system via a video cable that connects to the fluoroscope video output.
- [033] 3- Dewarping of acquired image: As described in many scientific papers, the fluoroscope images may contain distortions caused by optical

characteristics of the system, external magnetic fields, etc... These distortions would reduce the accuracy of the navigation, particularly in the image extremities. It is therefore important to remove these distortions.

[034] The distortion-removing algorithms use some of the beads/wires from the calibration object. Since these beads/wires are contained in the image and placed in a particular pattern, it is possible to determine a mathematical transformation that dewarps the pattern in the image. This transformation is then applied to the remainder of the image. Naturally, to use this algorithm, it is necessary to detect the calibration object beads/wires within the image. To minimize operating room time required from the surgeon, this process is automated.

[035] 4- Calibration of image to tracking system coordinate system: The principle for this calibration is to establish the mathematical relationship between the patterns identified in the image (see previous step) and the beads/wires true position in space. Since the calibration object is tracked and the bead/wire pattern position and orientation relative to the tracker is known (see step 2), the beads/wires true position in space is also known.

[036] 5- Removal of calibration object patterns from image: Once the image is dewarped and calibrated, the calibration object patterns are no longer useful to the surgeon and need to be removed to insure that the surgeon's view is not limited.

[037] 6- Navigation of the surgeon's instruments on the fluoroscope images: The surgeon will do steps 2-5 as many times as needed until he has the images required for the surgery. At this point, other objects tracked by the system may be superimposed on the images obtained from the fluoroscope. While this document describes the navigation as intended for a pedicle screw insertion in the lumbar spine, a number of other navigation tools could be designed.

[038] To illustrate the principle of the present invention, the following example is

used. A virtual screw is inserted on the computer display of one of the surgeon's tracked tool. This visual representation will be used to plan how the surgeon will position his next screw and which screw size can be used safely. Figure 1 shows a graphic user interface with three virtual screws in the image. Once the surgeon is satisfied with the virtual screw position, an insertion axis will be displayed on the fluoroscope images to guide the surgeon for the drilling of the holes and the placement of the real screw. This procedure should be followed for all the screws to be placed on vertebrae where the patient reference is placed. When all the screw locations seen in the images have been determined and the screws placed, the surgeon can return to step 2 and repeat all of the following steps until the screws are all inserted. It is possible to save the fluoroscope images with an overlay of the final screw positions in a standard graphic format.

[039] The surgeon may place virtual implants on multiple bones. For example, the surgeon may place virtual screws on all of the vertebrae in one fluoroscopy image. He places his pointing tool on the chosen entrance point for each screw based on his knowledge of the patient's anatomy and his navigation system. On the screen of the navigation system, he can see the virtual screws and adjust the diameter of each screw in order to ensure that the screw will not be larger than the pedicle and will be oriented in such a way as to be completely contained within the bone. The virtual screws can be aligned with respect to the bones, or with respect to each other. The virtual screws can then be fixed in place in the image and graphical tools such as targets or bull's eyes can help the surgeon place the real implant in the planned area. Figure 2 shows an interface image wherein a bull's eye guides the drill of a surgeon for the placement of the screws.

[040] By placing multiple virtual implants in one image, planning tools allow the surgeon to better align the implants. For example, if the goal is to place the virtual screws in a straight line, a line can be traced on the screen between

two virtual screws, allowing the surgeon to properly align the subsequent screws and obtain the targeted rectilinear alignment. This can be seen in figure 3, where an interface image shows a straight line used to align two virtual screws together. Another example is in the case of multi-implant constructs, such as for scoliosis, which is an abnormal lateral curve of the spine. The surgeon can provide a rod of predetermined shape and the navigation system can then illustrate this rod with respect to the screws in order to indicate the optimal alignment. Alternatively, once the screws are placed, the navigation system can provide the optimal curve for the rod in order to facilitate insertion.

[041] Figure 4 shows an embodiment of the apparatus according to the invention. A display user interface 40 receives command data from the user via a tool 42 manipulated by the user. The tool 42 can be a pointer which touches the screen directly, a computer mouse that controls a cursor on a display, or any other type of tool that allows the user to interface with the graphics on the display. From the user interface 40, the user can access a database of virtual implants 44. The database 44 comprises all the possible sizes and shapes of implants available for the surgery.

[042] The apparatus also comprises a positioning module 46. The positioning module 46 can detect where a virtual implant has been placed by the user and determine its position in a reference frame. It can also calculate where a second virtual implant should be placed with respect to the position and orientation of the first virtual implant. If two virtual implants have been placed, it can determine where a third virtual implant should be placed in order to match an alignment of the first two virtual implants. If the placement of a third virtual implant is impossible given the anatomy of the patient and the position of the first two virtual implants, the positioning module 46 can group together the first two implants and move them in position and orientation together in order to align them with a placement of the third virtual implant. The

positioning module 46 can also calculate what size or shape the third virtual implant should be in order to properly fit with the alignment imposed by the placement of the first two virtual implants. The positioning module 46 can also adjust individually the first two virtual implants in order to better co-exist with the third virtual implant. It can be appreciated that three virtual implants are used to demonstrate the capabilities of the positioning module 46 and should not in any way limit the scope of the module. Relative position data is exchanged between the user interface 40 and the positioning module 46. An image storer 43 comprises images of the patient anatomy and transmits patient anatomy data to the user interface 40 for the user to view and to the positioning module 46 for the module to use the data in its calculations and placement operations. The positioning module 46 can select an ideal virtual implant from the virtual implant database 44.

[043] Figure 5 is a flowchart of the method of the present invention. The first step consists in providing an image of patient anatomy 50. This can be done pre-operatively or intra-operatively. The next step is to select a virtual implant for the database of virtual implants 51. Once selected, the user is to place the virtual implant at a desired location in the image 52. These first three steps (50, 51, 52) are repeated for subsequent virtual implants. However when a subsequent implant is positioned, the position of a preceding virtual implant is taken into account in order to place the subsequent virtual implant 53. Automated planning tools are used to determine the position or shape of the subsequent virtual implant with respect to the preceding virtual implant.

[044] To illustrate step 53, the case of a spinal intervention is used. If a first virtual implant is a pedicle screw, the surgeon selects it from the database and places it in the image. The second virtual implant can also be a pedicle screw. However its placement is determined based the position and orientation of the first virtual pedicle screw. If a straight alignment is desired, then the second pedicle screw is placed so as to obtain a straight line from

the first pedicle screw to the second pedicle screw. If a third virtual implant is a rod to be fitted on the screws, the shape of the rod is determined based on the placement of the first two pedicle screws. If the anatomy is limiting and doesn't allow many configurations or shapes for the rod, then the virtual rod is placed in the image according to the constraints of the anatomy and the virtual pedicle screws are then adjusted based on the position of the rod.

[045] Therefore, lines are used to join together the virtual implants and align them on the image 54. The method also comprises calculating a location for the subsequent virtual implant based on a location of the preceding virtual implant 55 and re-adjusting a position of a preceding virtual implant to better position the subsequent virtual implant 56. The last step of the method consists in placing the real implants based on the position of the virtual implants in the image 57.

[046] In an alternate embodiment, other interventions like intramedullary nailing may be addressed with these planning tools. In this case, the planning tools can be used to align the intramedullary rod with the proximal and distal nails during a fracture correction surgical intervention in order to allow the least invasive method without the presence of a cumbersome mechanical jig. Once the tracked rod is placed in the bone, virtual nails with graphic aiming devices can be placed to orient the positioning of the real implants such that they can pass through the holes in the rod (normally not visible to the surgeon). Additionally, in the case of a multi-fragment fracture, similar planning methods could be used to reposition virtual fragments obtained from intra-operative imaging and apply virtual nails or other relevant implants. The potential interventions cover all surgeries with multiple implants including but not restricted to orthopedics (spine, hip, knee, shoulder, etc) and ear-nose-throat (ENT).

[047] In a preferred embodiment, the planning module 45 is used with a computer assisted surgery system 48 and a tracking module 47, as illustrated in figure

6.

[048]

It will be understood that numerous modifications thereto will appear to those skilled in the art. Accordingly, the above description and accompanying drawings should be taken as illustrative of the invention and not in a limiting sense. It will further be understood that it is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice within the art to which the invention pertains and as may be applied to the essential features herein before set forth, and as follows in the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A method for placing multiple implants during a surgery using a computer aided surgery system, the method comprising:
 - (a) providing an image representing a patient's anatomy;
 - (b) selecting a virtual implant from a database of virtual implants;
 - (c) placing said virtual implant in said image;
 - (d) repeating steps (a) to (c) for subsequent virtual implants, taking into account a position of a preceding virtual implant to place a subsequent virtual implant using automated planning tools in said computer aided surgery system to determine one of a position and a shape of the subsequent virtual implant with respect to the preceding virtual implant; and
 - (e) placing said multiple implants according to said virtual implants in said image using said computer aided surgery system.
2. A method as claimed in claim 1, wherein said determining one of a position and a shape of the subsequent virtual implant further comprises using lines to join together said virtual implants and align them on said image representing a patient's anatomy.
3. A method as claimed in claim 1, wherein said determining one of a position and a shape of the subsequent virtual implant further comprises calculating a location for said subsequent virtual implant based on a location of said preceding virtual implant.
4. A method as claimed in claim 3, wherein said determining one of a position and a shape of the subsequent virtual implant further comprises constraining said one of a position and a shape based on constraints imposed by said preceding virtual implant.

5. A method as claimed in claim 1, further comprising re-adjusting a position of said preceding virtual implant to better position said subsequent virtual implant in order to achieve an optimal alignment of all of said virtual implants.
6. An apparatus for planning a surgery, the apparatus comprising:
 - a display for an image representing a patient's anatomy;
 - a database of virtual implants from which a user selects;
 - a tool for the user to manipulate in order to select the virtual implants from the database and place them in the image at chosen locations; and
 - a positioning module to calculate a position of one of the virtual implants with respect to another of the virtual implants and allow the user to align the virtual implants with respect to each other for said planning a surgery.
7. An apparatus as claimed in claim 6, wherein said positioning module has a display module to indicate relative position data.
8. An apparatus as claimed in claim 6, wherein said positioning module has a vector module to move virtual implants according to its calculations.
9. A computer aided surgery system for placing implants comprising an apparatus for planning a surgery as defined claims 6 to 8 and a tracking module for tracking tools during said surgery.

ABSTRACT

A method and an apparatus are described for placing multiple implants during a surgery, the apparatus comprising: a display for an image representing a patient's anatomy; a database of virtual implants from which a user selects; a tool for the user to manipulate in order to select the virtual implants from the database and place them in the image at chosen locations; and a positioning module to calculate a position of one of the virtual implants with respect to another of the virtual implants and allow the user to align the virtual implants with respect to each other for said planning a surgery.

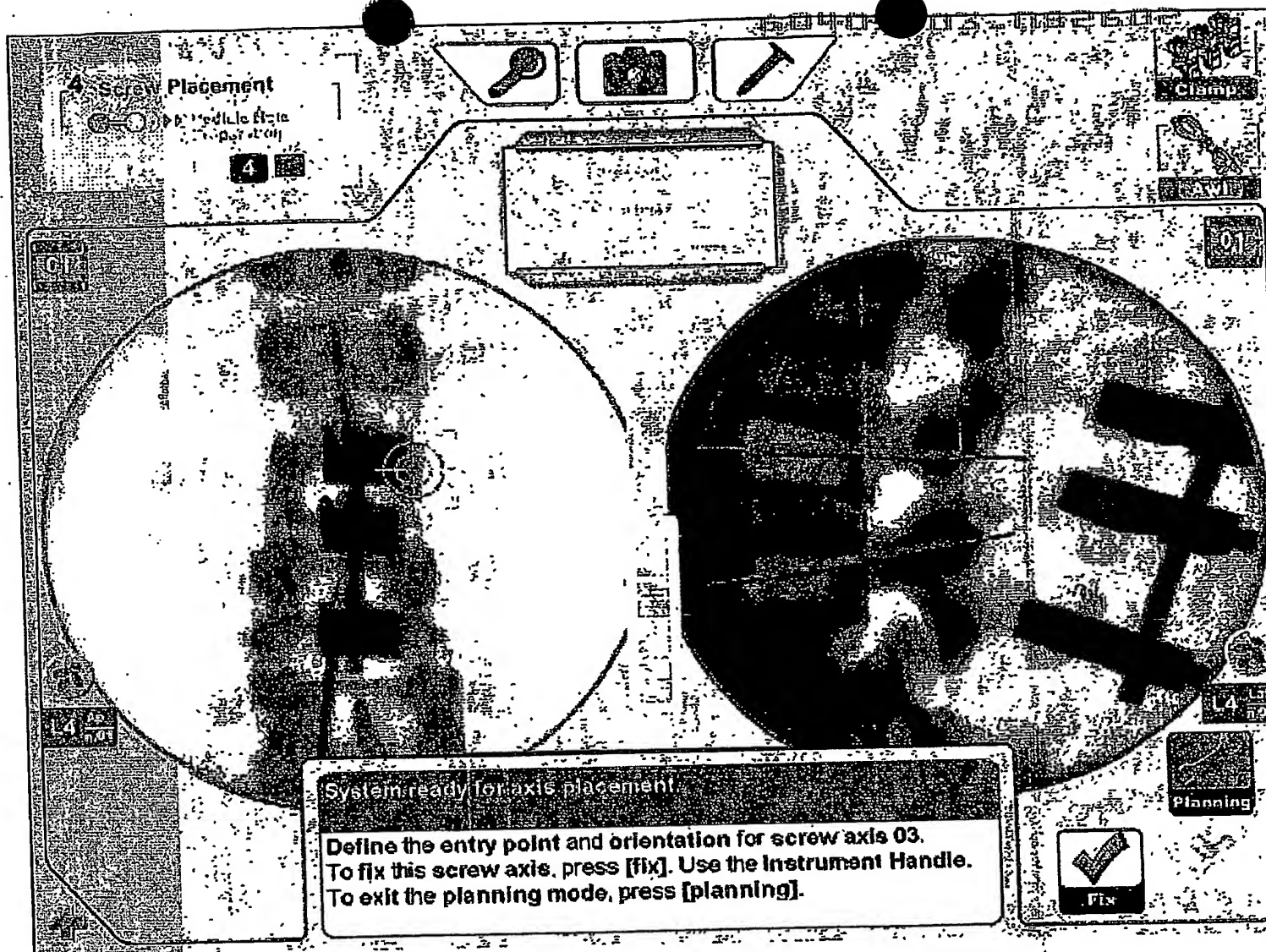


FIGURE 1

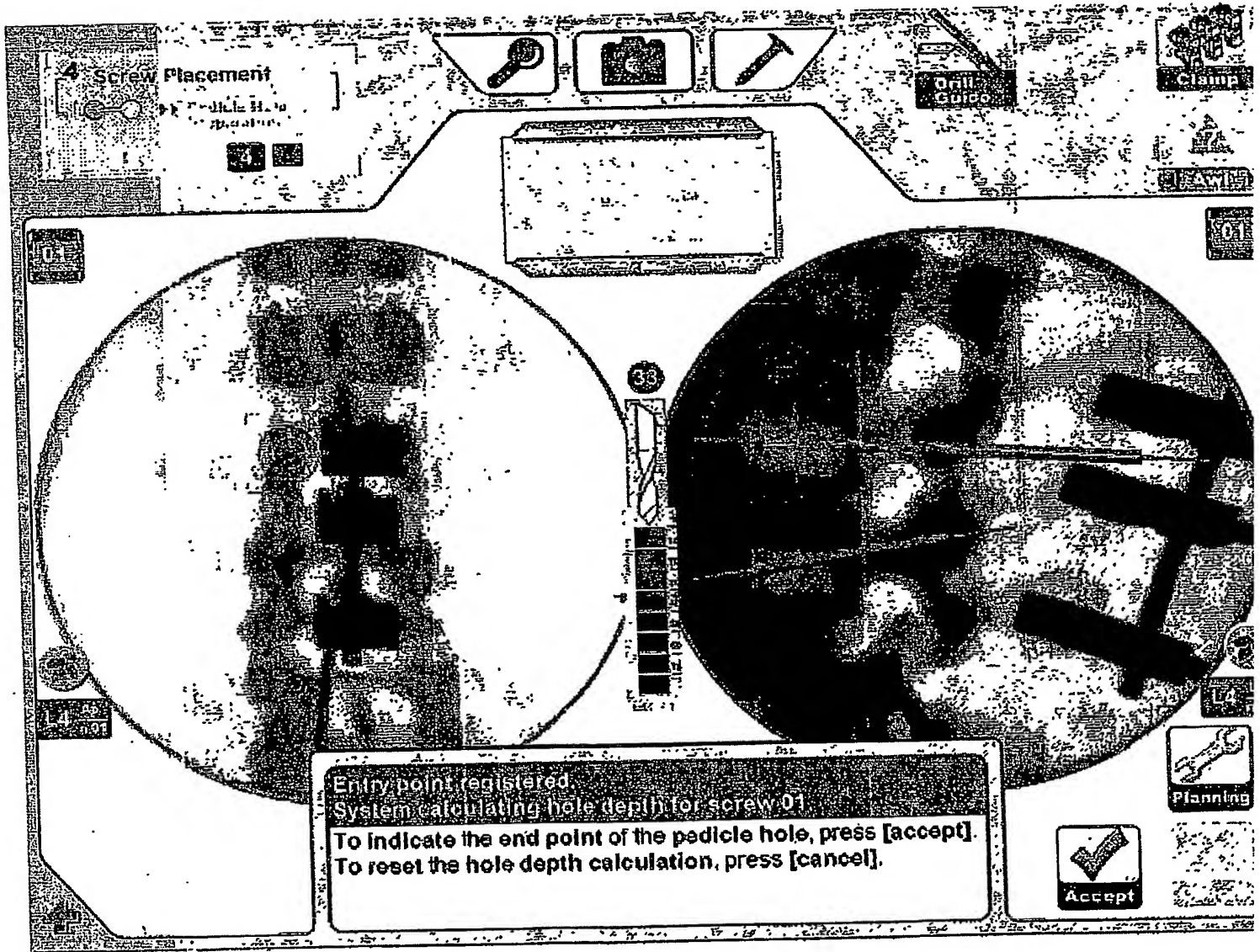


FIGURE 2

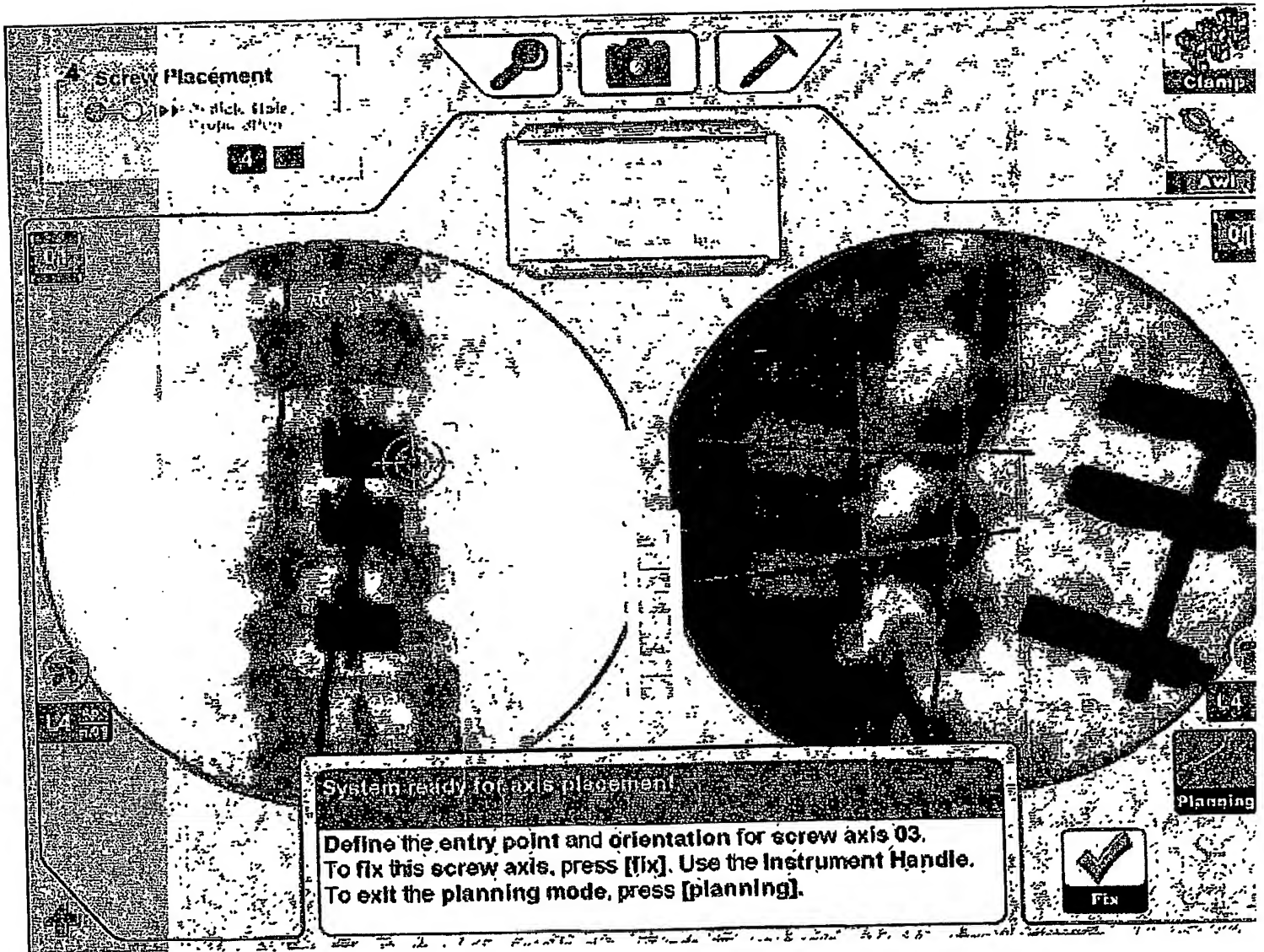


FIGURE 3

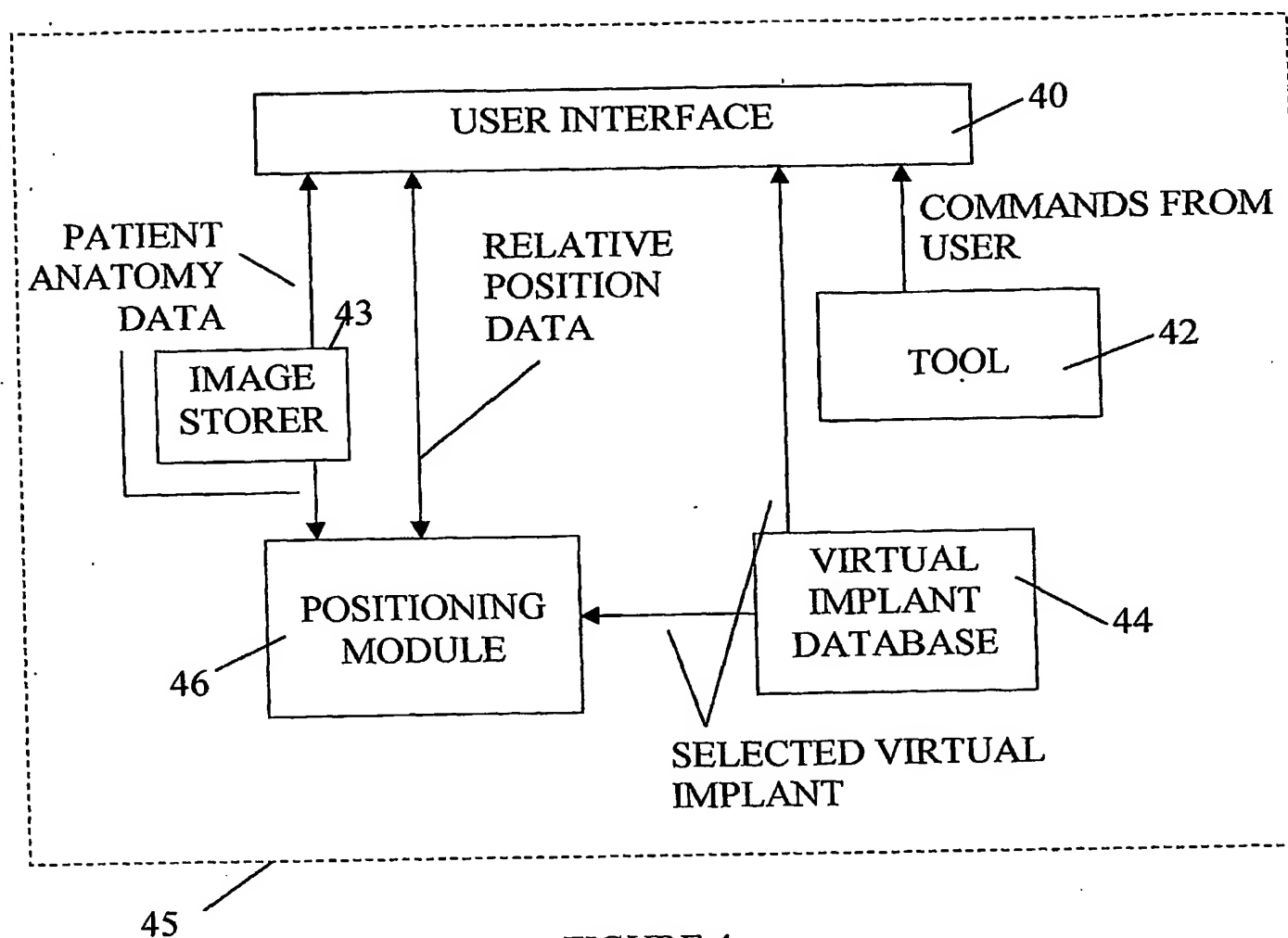


FIGURE 4

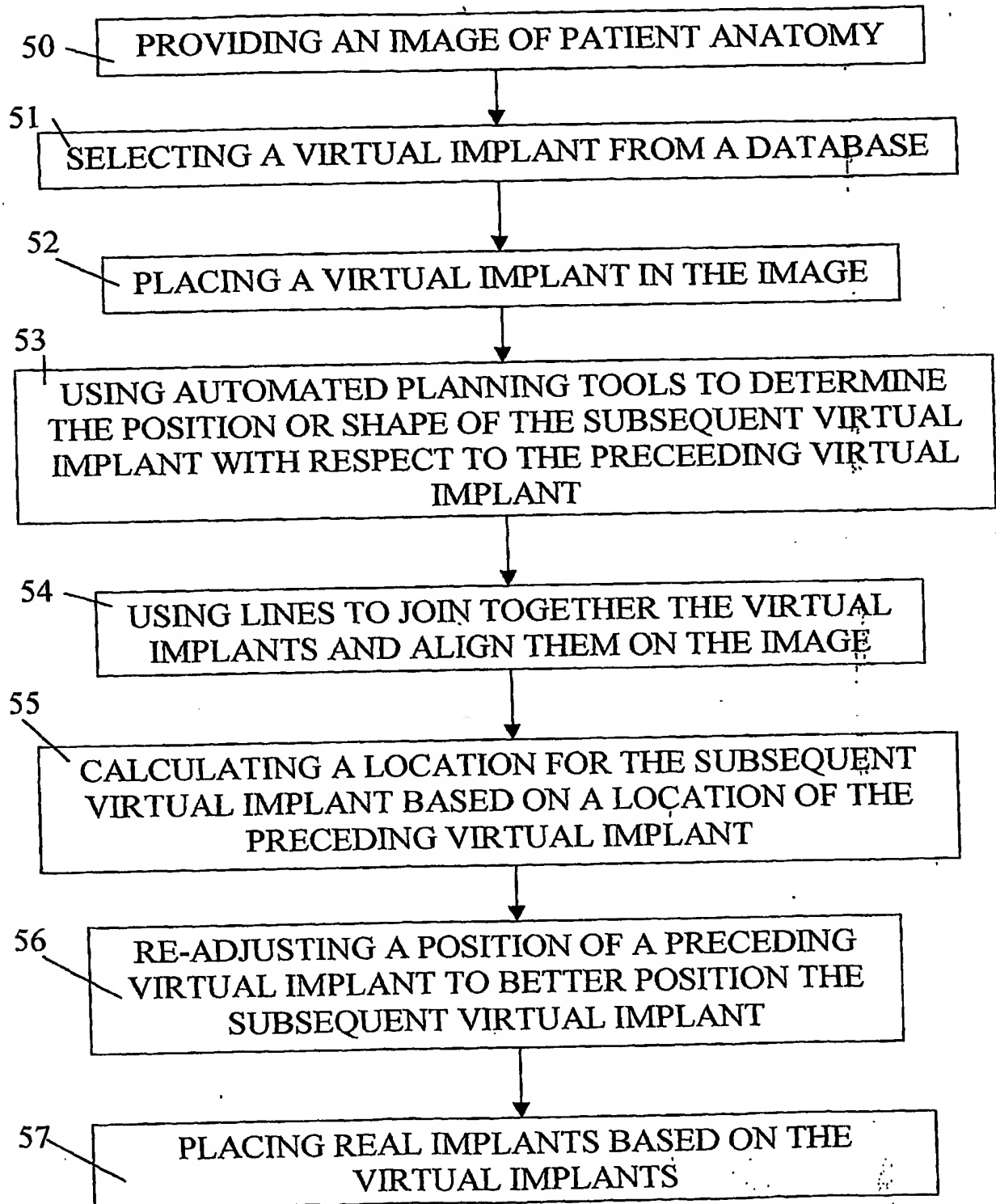


FIGURE 5

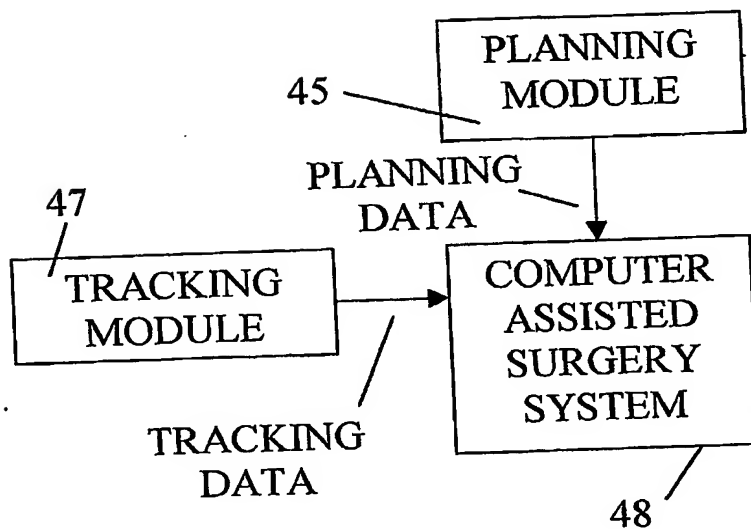


FIGURE 6

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